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For	:	CUSTOM ORTHODONTIC APPLIANCE FORMING METHOD AND APPARATUS	

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Via EFS-WEB

DECLARATION OF ERIC CHAPOULAUD

I, Eric Chapoulaud, hereby declare and state as follows:

1) I am a former employee of Ormco, the assignee of the above-noted patent application. I have been employed as a consultant by Ormco since leaving its employment. I am being compensated at a rate of $130 per hour for my efforts in connection with researching the facts set forth in this declaration.

2) I am one of the three inventors named in the above-noted patent application.

3) This application is one of several applications derived from a provisional application filed by our attorneys in late 1999, relating to the work done at Ormco over the course of several years preceding those filings.

Certificate of Electronic Filing

I hereby certify that this correspondence and any enclosures are being send electronically via EFS-WEB to the United States Patent and Trademark Office on the date indicated below.

Thomas W. Humphrey
Reg. No. 34,353

4.21.2009
Date

4) The work that led to the provisional application filed in 1999, was known as the Elan project.

5) The following reviews the development history for various aspects of the Elan project, referencing documents known to me and attached to this declaration. The documents establish the various points in time of the history provided below.

6) The Elan project featured the development of software having the purpose of designing customized brackets that could be fitted to the patient's teeth. The Elan software included an extensive graphical interface for imaging the shapes of teeth, selecting landmarks on the tooth shapes to define a desired tooth repositioning, and then creating customized brackets that would guide the teeth to the desired final positions.

7) In the original versions of the Elan software, developed up to the Summer of 1996, the brackets were customized for the desired tooth positions, by placing "vanilla", or slotless, brackets into a computer controlled milling machine, that would cut customized slots according to the desired tooth repositioning (the customization would involve establishing the torque to be applied by the archwire to the bracket, and the rotation, if any, to be achieved). This technique did not, however, permit the bracket pad to be customized to the tooth surface shape.

8) In the Summer of 1996, Craig Andreiko and I began working on methods to enable the Elan software to directly manufacture customized brackets using rapid prototyping technology. Ultimately, these efforts led to the conception of a method for creating

customized brackets by a procedure involving stereolithographic printing of bracket shapes in wax, which were converted to metal casts using an investment casting method.

9) The stereolithographic method for printing three dimensional structures was well developed at that time, and machines for creating three dimensional structures with this method were available on the market. This approach had not been applied to orthodontics up to that time, to my knowledge.

10) Furthermore, the investment casting method that would be used to create brackets from wax patterns, was well known at that time, and used on a daily basis within Ormco for the creation of orthodontic appliances. The use of investment casting had not been applied to creating bracket pads customized to tooth shapes up to that time, to my knowledge.

11) Exhibits A, B, C, D, E and F attached hereto document the development and prototyping of this customized bracket manufacturing method.

12) Exhibit A are photographs of a wax bracket dated June 18, 1996 and July 10, 1996. These brackets were made by me at the offices of the West Coast distributor of Sanders Prototype Inc. of Wilton, N.H., working with their sales personnel. The brackets were evaluated by Ormco and were generally well received as discussed below.

13) The July photograph in Exhibit A shows a part made only of green colored "structural" wax, which is the finished product. Immediately after the printing process, the green structural wax that forms the finished part, is encased in red colored "support" wax. The red support wax is washed away from the green structural wax after printing, to produce

the finished part. In the June photograph, a bracket with some remaining support wax (colored red) can be still be seen.

14) This test of the use of stereolithography to create orthodontic appliances was considered successful. I pursued the matter further via a visit to Sanders' New Hampshire facility. The purpose of this visit was to discuss the stereolithographic equipment sold by Sanders and its adaptation for production line creation of customized orthodontic appliances, specifically, customized brackets.

15) Exhibits B and C are travel requests in which I am working on plans to visit Sanders in July and August.

16) I ultimately visited Sanders in November of 1996. Exhibit D is an expense report I submitted for the trip I took to Sanders in November of 1996, during which I evaluated the Sanders equipment.

17) Exhibit E is a trip report prepared by me reporting the results of my visit to Sanders in early November 1996. Notably, this report references, in the second paragraph, the tests I conducted with the West Coast Sanders distributor, which involved creating parts using Elan application software. These tests were considered successful and had generally good results.

18) Exhibit E, at the bottom of the first page, further describes the stereolithographic methods used by the Sanders equipment: as I explain there, the machine "deposit[s] thermo-wax droplets in successive layers allowing the build of 3D Objects from ground up."

19) Exhibit E, at the top of the second page, details the use of structural wax and support wax to build parts in a layer-by-layer fashion, as I explain above.

20) Exhibit E confirms that Sanders had a machine known as the "Model Maker" available for purchase in November 1996, and had plans to introduce an upgraded machine, the "Model Maker II", in 1997. I negotiated an arrangement to purchase the "Model Maker" and upgrade it to a "Model Maker II" when the new machine became available.

21) The third page of Exhibit E documents my belief that I would be able to use the Elan programs that I had written, to create CAD models for direct fabrication of brackets with the Model Maker. My memo specifically states "Using the 3D Modeler, we can design a software that creates completely the brackets, according to the particular dimensions of each tooth, and send these design [sic] to the Wax printer to create a master to use to cast the finished part. This is a new and specific application for Sanders."

22) Exhibit E documents my further successful testing at Sanders. On the third page it states "we have been able to manufacture a sample of two different one piece brackets that were designed by us. These parts are the most complex parts that we have asked Sanders to make. Most particularly, their pads includes [sic] a collection of little "pegs" of 0.015 x 0.015 inches. These are very little details that are correctly reproduced by the machine."

23) Exhibit F is a capital appropriation request I submitted to request that Ormco allocate capital to purchase the Sanders Model Maker / Model Maker II for use in the Elan project. Exhibit F explains on the second and third pages that the Sanders machine had successfully created a three-dimensional bracket from a CAD design, and explains my

anticipated use of the Sanders machine in automated creation of completely customized brackets including customized bracket pads to fit to the tooth shape. Specifically, the document explains that the Elan software would be improved to allow customization of bracket pads to accomplish a further improvement over the existing methods.

24) The Exhibit F capital request explains on the first page that the Model Maker would permit the Elan software to be used to directly fabricate custom brackets rather than using a milling technique to customize the brackets.

25) Progress in development of the Elan software to create 3D models for brackets, and to control the Sanders machine, continued through early 1997. This progress is documented in the product development reports issued by Albert Ruiz-Vela, a manager at Ormco, which was copied to myself and the other inventors. The reports of Exhibits G, H, I, J, K. L and M report on activity from December 1996 through June of 1997.

26) Exhibit G illustrates (page 4) that in December 1996, Ormco was calibrating a scanner for the purpose of scanning tooth images which would be used in creating customized brackets and pads.

27) Exhibit H illustrates (page 4) that in January of 1997, Ormco had the scanner operational.

28) Exhibit I illustrates (page 4) that in February of 1997, a three dimensional scan of an upper jaw of a standard model ("P.K. THOMAS") was performed, and functions were developed in the Elan software to position CAD representations of standard "Spirit" brackets on the model of the scanned teeth. A set of brackets for an appliance was set-up on the model, and a wire to fit within those brackets was mathematically computed.

29) Exhibit J illustrates (page 4) that in March of 1997 a case of 5x5 brackets for the upper teeth of the P.K. THOMAS model was created "manually" using CAD software; the wire and the bracket positions and characteristics (torque, in/out and RIS) were developed as part of this process. Software for automating the wire design was specified.

30) Exhibit K illustrates (page 4) that in April of 1997 a plate was milled to thermoform the wire for the brackets defined in the previous month, and Jig design software was developed that would create bracket placement jigs for brackets. A prototype jig was milled for the upper right cuspid of the P.K. THOMAS case and was verified to have the correct precision.

31) Exhibit L illustrates (page 4) that in May of 1997, the Sanders machine arrived from New Hampshire, and was set up for use at Ormco. Also in that month, Ormco "[p]roduced wax parts of Upper Lateral brackets in different sizes: real life, scale 10 and currently scale 20." The immediately following goals for June were to "produce customized wax patterns of brackets and JIGS, using the Elan Software."

32) Exhibit M illustrates (page 4) that in June of 1997, "Software modules to create brackets from dimensions, torque, In/out and RIS was started [sic] from a previous prototype written in 1995". While this Elan software was being developed, I "[c]ontinued producing parts with the [Sanders Model Maker software] MM6 Pro".

33) At approximately this time (June 1997), I used a manual process to create customized brackets, using a "subtraction" method. Specifically, in the CAD software, a standard bracket pad was placed against the patient's tooth, so that each point in the outer

perimeter of the pad was at or below the tooth surface. Thereafter, any portion of the bracket that was beneath the surface of the tooth was removed, to form a customized bracket pad shape.

34) While this process was effective to create model brackets that matched tooth crown surfaces, it resulted in bracket pads of uneven thickness. (A slide that is part of Exhibit N, which became Fig. 5G, clearly shows brackets with uneven pad thickness, that were created by the subtraction method described above.) This subtraction method was subsequently replaced with an automated and more robust method that created even bracket pad thickness, as noted below.

35) By May of 1997, a set of brackets had been cast from wax prototypes created by stereolithography with the Sanders machine. As stated in Exhibit L, the accomplishments of May of 1997 included "Produced wax parts of Upper Lateral brackets in different sizes: real life, scale 10 and currently scale 20."

36) Thus, by May of 1997, I was using Model Maker software, and had produced a set of brackets mounted to jigs by the stereolithography – wax investment casting method.

37) In June of 1997, a set of jigs were created for an Upper Lateral bracket set. In Exhibit M, the June progress report, it is stated that "[a] set of 5x5 Jigs have been manufactured after accuracy improvement of the manufacturing software. These jigs have been manually mounted with to their respective brackets. The case reveals good fit accuracy to the model."

38) During 1997, slides were taken for the purposes of presenting the progress of Elan. Images from a set of these slides are attached as Exhibit N. Several of the figures of the provisional application filed in 1999 were derived from these slides, and the corresponding figure numbers are shown in Exhibit N.

39) Notably, among the slides in Exhibit N is a slide of the set of jigs created for the P.K. THOMAS model in June of 1997. Specifically, the slide shows a set of jigs dated June 11, 1997. This slide became Figure 6A of the provisional application, although the figure does not include the June 11, 1997 date that was written on the original set of Jigs. This June 11, 1997 date is documentation of the prototypes for the P.K. THOMAS tooth model mentioned in Exhibit M, although the brackets are not attached to the jigs seen in the slide.

40) At the time I was creating customized jigs and manually creating brackets as described above, I was also refining my automated bracket creation software, first written in 1995, to automatically create brackets shaped for tooth surfaces. This effort continued through June and into July 1997. As part of this effort and refining our use of the Sanders Model Maker, I also attended training at Sanders.

41) The following table illustrates, with reference to Exhibits A through M, how Ormco had successfully implemented or "reduced to practice" the methods recited in the claims of the application.

42) Exhibits O, P and Q document my activity in July of 1997 to further develop and prepare the prototyped system for production.

43) Exhibit O is an expense report from a trip I took to Sanders in July of 1997 to receive training on the Model Maker II, which was soon to be brought to Ormco in accordance with the agreed upgrade.

44) Exhibit P is an expense report for my purchase of an extension cable, needed to install the Model Maker II. This documents that the Model Maker II was received and installed at Ormco on or about July 21.

45) Exhibit Q is a progress report that documents the activity of July of 1997. This report shows (page 4) that I had been trained at Sanders and the Model Maker II was installed in July of 1997.

46) Furthermore, Exhibit Q documents that my custom software reached a level of completion where it could not only create customized brackets, but also create brackets in a "tree" form. Forming brackets in a tree allowed Ormco to create multiple brackets in a single cast. At this point, the software was considered both fully "developed and tested".

47) Exhibit Q also documents that the software was complete and able to create customized bracket designs automatically. This is established by the statement that "The Bracket design has also been improved to include constant pad thickness, lower gingival wing, rounded corners on the pad". These enhancements and improvements refer to the replacement of the manual, "subtraction" method for custom formation of brackets, with an improved automated method in which pads of constant thickness, conforming to tooth shape, would be automatically created by software.

48) Based on the foregoing, I recall and have confirmed from the documents that software for the automated creation of brackets with pads conforming to tooth shape, was developed and available at Ormco no later than the date of the Exhibit Q report, which is July 30, 1997. I recall working diligently on a daily basis through June and July of 1997 to develop this system, which was my central work project at the time.

49) The table set forth below details a correspondence of claim language of U.S. Patent 09/941,151 in comparison to the system developed at Ormco as described above.

CLAIM LANGUAGE	CORRESPONDING ORMCO ACTIVITY
1.A method of providing a custom orthodontic appliance based on the anatomy of an individual patient wherein the appliance has a three-dimensional surface having a shape matching the shape of at least a portion of an crown of at least one tooth of the individual patient, the method comprising:	As seen in Exhibit F, the purpose of acquisition of the Model Maker was to create brackets with "customization, in the Pad shape, dimension and adhesion surface" so as to match the crown of a tooth of the patient.
producing three-dimensional digital data of shapes of crowns of a plurality of teeth of an individual patient;	As seen in Exhibit Q, this step was accomplished no later than July 30, 1997, having been diligently pursued throughout at least June and July of 1997.
manufacturing a custom orthodontic appliance having a three-dimensional surface having a shape matching the shape of at least a portion of the crown of at least one tooth of the individual patient, based on the digital data, by a process that includes:	As seen in Exhibit M, in June of 1997 Ormco was already producing parts from the Model Maker using Sanders' MM6 Pro software, and a set of jigs had been manually mounted with brackets made in this manner.
manufacturing at least one intermediate object by depositing material, in accordance with the digital data, layer by layer in a plurality of layers, each layer containing a cross section having an edge defined by the digital data in the shape of at least one crown of a tooth of the	As best explained in Exhibit E on page 1, the Sanders Model Maker machine, used by Ormco to make wax brackets as early as June of 1996, is "adapted to deposit thermo-wax droplets in successive layers allowing the build of 3D Objects from ground up". As stated in

CLAIM LANGUAGE	CORRESPONDING ORMCO ACTIVITY
individual patient, the layers being stacked so the edges form a three-dimensional surface having a shape matching the shape of at least a portion of the crown of at least one tooth of the individual patient; and,	Exhibit F, page 1, the purpose of this process was to "add further customization, in the Pad shape, dimension and adhesion surface for example", thus matching the bracket shape to a three dimensional surface of a tooth.
using the intermediate object to form the custom orthodontic appliance having a three-dimensional surface matching the shape of at least a portion of the crown of at least one tooth of the individual patient.	As noted in Exhibit F, page 3, the use of the 3D Modeler was to "create[] completely the brackets, according to the particular dimensions of each tooth, and send these design to the Wax printer to create a master to use to cast the finished part."
3. The method of claim 1 wherein the manufacturing of the at least one intermediate object includes: depositing the material into the plurality of layers to form the cross sections of the intermediate object wherein the intermediate object is a mold having thereon the three-dimensional surface having the shape matching the shape of at least a portion of the crown of at least one tooth of the individual patient; and using the mold to form the custom orthodontic appliance having a three-dimensional surface matching the shape of at least a portion of the crown of at least one tooth of the individual patient.	The investment casting process used to create metal brackets from deposited wax involved the use of the wax bracket as a mold with a three dimensional surface matching the crown of a patient's teeth, which would then be used to form a metal cast of the bracket as completed in June of 1997 as documented in Exhibit M.
6. A method of providing a custom orthodontic appliance based on the anatomy of the individual patient wherein the appliance has a three-dimensional surface having a shape matching the shape of at least a portion of the crown of at least one tooth of the individual patient, the method comprising:	As seen in Exhibit F, the purpose of acquisition of the Model Maker was to create brackets with "customization, in the Pad shape, dimension and adhesion surface" so as to match the crown of a tooth of the patient.
producing three-dimensional digital data of shapes of the crowns of a plurality of the teeth of an individual patient;	As noted in Exhibits G and H, a 3D scanner was used by Ormco to capture the shapes of teeth; in the prototyping stage the standard P.K. THOMAS model was used.

CLAIM LANGUAGE	CORRESPONDING ORMCO ACTIVITY
manufacturing the custom orthodontic appliance having a three-dimensional surface having a shape matching the shape of at least a portion of the crown of at least one tooth of the individual patient, based on the digital data, by a process that includes:	As seen in Exhibit M, in June of 1997 Ormco was already producing parts from the Model Maker using Sanders' MM6 Pro software, and a set of jigs had been manually mounted with brackets made in this manner.
depositing material, in accordance with the digital data, into the plurality of layers to form the cross sections of a pattern having thereon the three-dimensional surface having the shape matching the shape of at least a portion of the crown of at least one tooth of the individual patient;	As best explained in Exhibit E on page 1, the Sanders Model Maker machined used to make wax brackets in June of 1997, is "adapted to deposit thermo-wax droplets in successive layers allowing the build of 3D Objects from ground up". As stated in Exhibit F, page 1, the purpose of this process was to "add further customization, in the Pad shape, dimension and adhesion surface for example", thus matching the bracket shape to a three dimensional surface of a tooth. As noted in Exhibit F, page 3, the use of the 3D Modeler was to "create[] completely the brackets, according to the particular dimensions of each tooth, and send these design to the Wax printer to create a master to use to cast the finished part."
using the pattern to form a mold having a three-dimensional surface matching the shape of at least a portion of the crown of at least one tooth of the individual patient; and	The investment casting process used to create metal brackets from deposited wax involved the use of the wax bracket in forming a mold in sand having a three dimensional surface matching the crown of a patient's teeth, which would then be used to form a metal cast of the bracket. I recall the use of this investment casting method to make metal version of wax bracket patterns produced by the Sanders Model Maker, as soon as the Model Maker became available. The accomplishment of this step at least by June of 1997 is documented in Exhibit M.
using the mold to form the custom orthodontic appliance having a three-dimensional surface	The sand mold created by the well known investment casting process was used to cast

CLAIM LANGUAGE	CORRESPONDING ORMCO ACTIVITY
matching the shape of at least a portion of the crown of at least one tooth of the individual patient.	metal brackets.
7. The method of claim 6 wherein: the material is wax; and, the step of using the mold to form the custom orthodontic appliance includes investment casting the custom orthodontic appliance in the mold.	The Sanders machine created wax prototypes from "thermo-wax droplets" as explained in Exhibit E.
8. The method of claim 7 wherein the depositing includes: depositing the wax by a jet printing method in response to the three-dimensional digital data of shapes of the crowns of a plurality of the teeth of an individual patient.	Exhibit E explains that the Model Maker uses "the same technology used in 'inkjet printers'".
9. The method of claim 6 wherein the depositing of the material includes depositing by a stereo lithography process.	Exhibit E, first paragraph, identifies the technology as "stereo-lithography"
11. The method of claim 1 wherein the custom orthodontic appliance has at least one three dimensional surface that is configured to matingly conform to at least a portion of the crown of a tooth of the individual patient	As explained in Exhibit F, the customization with wax printing "will allow Elan to create full customization including the Pad shape for example."
12. The method of claim 1 wherein the depositing includes: depositing the material by a jet printing method in response to the three dimensional digital data of shapes of the crowns of a plurality of the teeth of an individual patient.	Exhibit E explains that the Model Maker uses "the same technology used in 'inkjet printers'".
13. The method of claim 1 wherein: the custom orthodontic appliance is an orthodontic bracket having a three dimensional surface having a shape matching the shape of at least a portion of the crown of at least one tooth of the individual patient.	The brackets are created to match the shape of the adhesion area of the tooth to which the bracket is mounted.
14. The method of claim 1 wherein: the custom orthodontic appliance is an orthodontic bracket positioning jig having a	The possibility of creating jigs by rapid prototyping was discussed at various times during the Elan development, however, the jigs

CLAIM LANGUAGE	CORRESPONDING ORMCO ACTIVITY
three dimensional surface having a shape matching the shape of at least a portion of the crown of at least one tooth of the individual patient.	used in the various events documented above were created by a milling process.
16. The method of claim 1 wherein: the material is selectively formed in each layer of a first portion of the material that is removable chemically, thermally or mechanically, and a second portion of the material that remains after removal of the first portion, the second portion of the material having a surface conforming to the shape of at least the portion of the crown of the at least one tooth of the individual patient.	As noted above, the wax bracket patterns created with the Sanders Model Maker were green structural wax, encased in red structural wax. The red support wax was then removed.
18. The method of claim 1 wherein: the depositing of the material includes selectively jetting portions of the material layer by layer to produce two dimensional cross sections.	As best explained in Exhibit E on page 1, the Sanders Model Maker machined used to make wax brackets in June of 1997, is "adapted to deposit thermo-wax droplets in successive layers allowing the build of 3D Objects from ground up".
20. The method of claim 1 wherein the depositing of the material is depositing by a stereo lithography process.	Exhibit E, first paragraph, identifies the technology as "stereo-lithography"

50) Exhibit R illustrates (page 4) that in August 1997, an automatic link was created between the software for computing an orthodontic set-up (desired bracket placement) and the software for making customized brackets. Further, using the integrated software, a new set of ten brackets for the upper teeth of the P.K. THOMAS case was calculated. Software was also built to form brackets into trees for investment casting. Further, a scan of the lower jaw of the P.K. THOMAS model was captured to allow the creation of a lower jaw bracket and jig set.

51) Exhibit S illustrates (page 4) that in September 1997, software for setup of a lower jaw was created, as a preliminary to creating brackets for the lower jaw of the P.K. THOMAS model. Further, the bracket trees defined in August 1997 were printed in wax for subsequent casting to validate that part of the process.

52) Exhibit T illustrates (page 4) that in October 1997 software was developed to set up the lower (mandible) teeth automatically, using the scanned images of those teeth.

53) As documented in Exhibits R, S and T, by the end of 1997, software had been fully developed to (1) scan both upper and lower teeth to create a 3D model, (2) set-up the teeth for orthodontic correction, (3) automatically create 3D customized bracket models from the set-up, and (4) automatically print the brackets in trees with the Sanders Model Maker II, so that the bracket trees could then be cast, and the brackets mated with jigs for installation on the teeth.

54) The visual interface of the software for this process is illustrated in the slides of Exhibit N. These slides were collected for an Ormco presentation of the developed technology in late 1997. As noted above, they were the basis for the figures in the present application and thus provide the same visual presentation of tooth shapes that is disclosed in the application.

55) For the purpose of computing a set-up of teeth, the software would allow an operator to identify landmarks on the images of the teeth of a patient by interaction on the screen. Based on these landmark features, the software would compute an idealized set-up of the teeth, i.e., a corrected position for the teeth.

56) During my development of this software, in several instances I would use the software to landmark tooth images, and Dr. Andreiko would also use the software to landmark the same tooth images. The purpose of this exercise was to test the software's usability and its repeatability from one use to the next, and to evaluate the extent to which orthodontist expertise would influence set-ups.

57) Exhibits U and V attached hereto are color printouts of one exercise of the type described above. Exhibit U illustrates landmarks selected by Dr. Andreiko on February 12, 1998, on a set of tooth images. The consequent corrected tooth positions are also shown. In these printouts, the tooth surface images are not shown, however, the screen display could include or exclude tooth surface images. Exhibit V illustrates landmarks selected by myself on February 13, 1998, on the same tooth images as used by Dr. Andreiko in Exhibit U. It can be seen that the landmarks are somewhat different than those chosen by Dr. Andreiko, and the consequent corrected tooth positions are also different. Exhibit V includes the tooth surface images on a number of the printed pages.

58) The following table illustrates, with reference to Exhibits A through U, how Ormco had successfully implemented the methods recited in the claims U.S. Patent Application 10/868,311, at least by the February 13, 1998 date of Exhibit U:

CLAIM LANGUAGE	CORRESPONDING ORMCO ACTIVITY
120. A method of providing a custom orthodontic appliance for repositioning teeth of a patient, the method comprising:	The Elan software designed orthodontic appliances for repositioning of teeth of patients.
providing for display on a computer screen,	The Elan software would present a display of

CLAIM LANGUAGE	CORRESPONDING ORMCO ACTIVITY
with interaction by an operator, data of images of the teeth of the patient in suggested post-treatment tooth positions and orientations that are based on three-dimensional information of the shapes of the teeth of the patient;	images of tooth surfaces for a patient, as seen in Exhibit N. Exhibits G, H and I document that in late 1996 and early 1997, Ormco obtained, calibrated and successfully used a three dimensional scanner to create images of teeth (in the case of Exhibit I, an upper jaw the P.K. THOMAS model). These scanned images were displayed as seen in Exhibits U and V.
receiving feedback information on the suggested post-treatment positions and orientations from a person, other than the operator, who has interactively viewed a display of the provided images on the computer screen; and	The process documented in Exhibits U and V involved the creation of landmarks by me and the creation of feedback on those landmarks by Dr. Andreiko in the form of alternative landmarks that would alter the post-treatment positions.
providing a custom orthodontic appliance configured to reposition teeth of the patient based on the suggested tooth positions and orientations in accordance with the feed back information.	As explained above, Ormco created custom orthodontic appliances to reposition teeth in response to set-ups, no later than July of 1997 as documented in Exhibits A through N.
121. The method of claim 120 wherein: the person viewing the display of the images is an orthodontic practitioner; and the feedback information includes information of approval by the orthodontic practitioner of the suggested post-treatment tooth positions and orientations toward which the teeth of the patient are to be moved by the appliance.	In the various uses of the software described above, one of which is illustrated in Exhibits U and V, one of the persons involved was Dr. Andreiko, who is and was an orthodontic practitioner; in some experiments Dr. Andreiko would evaluate landmarks I applied and approve them, and in other experiments, changes would be made by Dr. Andreiko.
122. The method of claim 120 wherein: the feedback information includes information of a change in position or orientation of at least one tooth from the suggested post-treatment tooth positions and orientations toward which the at least one tooth of the patient is to be moved by the appliance.	Changes in landmarks created in the process exemplified in Exhibits U and V would change the position or orientation (or both) of one or more teeth in the "set-up" or post-treatment positions.
123. The method of claim 122 further comprising: providing revised images of the teeth of the patient for redisplay in revised post-treatment	Revised images of teeth in post-treatment positions were created whenever landmarks were changed by the process of Exhibits U and V, as is illustrated by comparing Exhibit U to

CLAIM LANGUAGE	CORRESPONDING ORMCO ACTIVITY
tooth positions and orientations based on the suggested tooth positions and orientations as changed in accordance with the feedback information.	Exhibit V.
124. A method of providing a custom orthodontic appliance configured to the individual anatomy of a patient for repositioning teeth of the patient, the method comprising:	The Elan software designed orthodontic appliances for repositioning of teeth of a patient, based on the individual anatomy of the patient.
providing for display on a computer screen images of the teeth of the patient in suggested post-treatment tooth positions and orientations that are based on three-dimensional information of the shapes of the teeth of the patient;	The Elan software would present a display of images of tooth surfaces for a patient, as seen in Exhibit N. Scanned images of teeth were displayed in post-treatment positions, generated based on the three dimensional shapes of the teeth, as seen in Exhibits U and V.
receiving feedback information on the suggested post-treatment positions and orientations from a person who has interactively viewed a display of the provided images on a computer screen wherein the feedback information includes one or more of:	The process documented in Exhibits U and V involved the creation of landmarks by me and the creation of feedback on those landmarks by Dr. Andreiko in the form of alternative landmarks that would alter the post-treatment positions.
information approving at least some of the suggested post-treatment positions and orientations , and	In experiments, one of Dr. Andreiko and I would evaluate landmarks of the other and accept them, which would maintain the post-treatment positions of the teeth.
information changing at least one of the suggested post-treatment tooth positions or orientations; and	In experiments, one of Dr. Andreiko and I would evaluate landmarks and change them, which would change the post-treatment positions of the teeth.
providing a custom orthodontic appliance configured to reposition teeth of the patient based on the suggested post-treatment tooth positions and orientations in accordance with the feedback information.	As explained above, in 1997 Ormco had already developed a process to create custom orthodontic appliances to reposition teeth in response to set-ups, in 1997 as documented in Exhibits A through N.
125. The method of claim 124 further comprising:	Revised images of teeth in post-treatment positions were created whenever landmarks

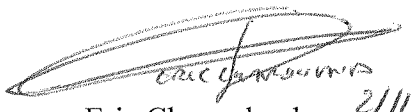
CLAIM LANGUAGE	CORRESPONDING ORMCO ACTIVITY
providing revised images of the teeth of the patient in revised post-treatment tooth positions and orientations based on the suggested post-treatment tooth positions and orientations as changed in accordance with the feedback information.	were changed by the process of Exhibits U and V, as is illustrated by comparing Exhibit U to Exhibit V.
126. The method of claim 125 further comprising: receiving from a person who has viewed a display of the provided revised images feedback information approving the revised post-treatment tooth positions and orientations toward which the teeth of the patient are to be moved by the appliance.	The process documented in Exhibits U and V involved the creation of landmarks by me and the creation of feedback on those landmarks by Dr. Andreiko in the form of alternative landmarks that would alter the post-treatment positions, and viewing by me of the altered positions.
127. The method of claim 124 further comprising: providing the person viewing the display with a capability to enter the feedback information.	The process documented in Exhibits U and V allowed either operator, viewing a tooth set-up, to input alternative landmarks.
128. The method of claim 124 wherein: the person viewing the display of the images is an orthodontic practitioner.	In the various uses of the software described above, one of which is illustrated in Exhibits U and V, one of the persons involved was Dr. Andreiko, who is and was an orthodontic practitioner.
129. A method of providing a custom orthodontic appliance, configured to the individual anatomy of a patient, for orthodontically repositioning teeth of the patient, the method comprising:	The Elan software designed orthodontic appliances for repositioning of teeth of a patient, using brackets configured for the individual anatomy of the patient.
providing digital data of suggested post-treatment tooth positions and orientations of teeth of the patient that are based on three-dimensional information of the shapes of the teeth of the patient;	The Elan software would present a display of images of tooth surfaces for a patient, in pre- and post-treatment positions, as seen in Exhibit N. These images generated based on the three dimensional shapes of the teeth, as seen in Exhibits U and V.
providing images of teeth of the patient from the digital data, for display on at least one computer screen to an orthodontic practitioner	In the various uses of the software described above, one of which is illustrated in Exhibits U and V, one of the persons involved was Dr.

CLAIM LANGUAGE	CORRESPONDING ORMCO ACTIVITY
in the suggested post treatment tooth positions and orientations for either (a approval for use in creating a custom orthodontic appliance for the patient or (b revision;	Andreiko, who is and was an orthodontic practitioner; in some experiments Dr. Andreiko would evaluate landmarks I applied and approve them, and in other experiments, changes would be made by Dr. Andreiko.
receiving from an orthodontic practitioner, who has interactively viewed on a computer screen a display of the provided images, feedback information approving the suggested post-treatment positions and orientations; and	The process documented in Exhibits U and V involved the creation of landmarks by me and the creation of feedback on those landmarks by Dr. Andreiko in the form of alternative landmarks that would alter the post-treatment positions.
providing a custom orthodontic appliance configured to the individual anatomy of the patient to reposition teeth of the patient based on the suggested post-treatment tooth positions and orientations approved in accordance with the feedback information.	As explained above, in 1997 Ormco had already developed a process to create custom orthodontic appliances to reposition teeth in response to set-ups, in 1997 as documented in Exhibits A through N.
130. The method of claim 129 wherein the receiving of the feedback information approving the suggested post-treatment positions and orientations for a custom orthodontic appliance for the patient includes: receiving from an the orthodontic practitioner, who has interactively viewed on a computer screen a display of the provided images, feedback information of revisions to the suggested post-treatment positions and orientations; providing further images of teeth of the patient based on the three dimensional information, for redisplay on the computer display device to the orthodontic practitioner, in suggested post-treatment tooth positions and orientations that have been changed in accordance with the feedback information of the revisions; and receiving from the orthodontic practitioner, who has viewed a redisplay of the provided further images on a computer screen, the	The process documented in Exhibits U and V involved the creation of landmarks by me and the creation of feedback on those landmarks by Dr. Andreiko in the form of alternative landmarks that would alter the post-treatment positions, and viewing by me of the altered positions.

CLAIM LANGUAGE	CORRESPONDING ORMCO ACTIVITY
feedback information approving the suggested post-treatment positions and orientations, as changed in accordance with the feedback information of the revisions.	
131. The method of claim 130 wherein: the providing of digital data of suggested post-treatment tooth positions and orientations of teeth of the patient that are based on three-dimensional information of the shapes of the teeth of the patient includes providing for display on a computer screen, with interaction by an operator, the digital data; and the orthodontic practitioner who has interactively viewed on a computer screen a display of the provided images is a person other than the operator.	The display of information by Elan utilized a computer screen as seen in Exhibit N and as printed in Exhibits U and V. In the experiments described above, I would often prepare landmarks to be viewed by Dr. Andreiko, as is seen in Exhibits U and V. In such cases, I would be the original operator defining landmarks, which would be subsequently viewed by Dr. Andreiko.
132. The method of claim 130 wherein: the receiving of feedback information from an orthodontic practitioner approving the suggested post-treatment positions and orientations includes receiving feedback information wherein the feedback information can include either information approving the suggested post-treatment tooth positions and orientations or information modifying at least one of the suggested post-treatment tooth positions or orientations .	In the various uses of the software described above, one of which is illustrated in Exhibits U and V, one of the persons involved was Dr. Andreiko, who is and was an orthodontic practitioner; in some experiments Dr. Andreiko would evaluate landmarks I applied and approve them, and in other experiments, changes would be made by Dr. Andreiko.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information and belief.

Respectfully submitted,



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